UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

This Document Relates to:

*All Actions*

Hon. Robert Kugler
Magistrate Karen Williams
Special Master Thomas Vanaskie

Civil Action No. 1:19-md-2875-RBK-JS

**PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO PRECLUDE DEFENSE EXPERT WILLIAM J. LAMBERT, PH.D., FROM OFFERING CLASS CERTIFICATION OPINIONS**

HONIK LLC
1515 Market St., Suite 1100
Philadelphia, PA 19102

KANNER & WHITELEY, LLC
701 Camp St.
New Orleans, LA 70130

GOLDENBERGLAW, PLLC
800 LaSalle Ave, Suite 2150
Minneapolis, MN 55402

On the Brief:
Ruben Honik, Esq.
David J. Stanoch, Esq.
Marlene Goldenberg, Esq.

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## I. INTRODUCTION

Aurobindo's opposition to Plaintiffs' Motion to exclude Dr. Lambert only further exposes the glaring weaknesses in Dr. Lambert's testimony. Dr. Lambert's opinions concerning (i) Aurobindo's compliance with current Good Manufacturing Practices (cGMPs), and (ii) the alleged value of Aurobindo's adulterated VCDs, remain unsupported and methodologically unsound.

Dr. Lambert testified that he deferred to the FDA's determination on whether Aurobindo was cGMP compliant.[1] In doing so, he admitted that Aurobindo's practices were *not* in compliance with cGMPs. Moreover, his opinions concerning Aurobindo's oversight of Lantech and testing for nitrosamines[2] are unreliable because there is too great an analytical gap between the data and the opinions proffered by Dr. Lambert. *General Elec. Co. v. Joiner,* 522 U.S. 136, 147 (1997) ("court may conclude that there is too great an analytical gap between the data and the opinion that is proffered").

Furthermore, Dr. Lambert's opinion regarding the supposed value of Aurobindo's VCDs, which he based on the VCDs' bioequivalence to the reference listed drugs, is of no help. Dr. Lambert made several admissions that negated his opinions on value. Dr. Lambert's failure to reliably apply his valuation methodology to the facts of the case, as well as his own admissions, renders his opinion unreliable.

## II. ARGUMENT

### A. Dr. Lambert's Testimony Concerning Aurobindo's Compliance with cGMPs Should Be Excluded Because It Lacks Good Grounds

Dr. Lambert's opinions concerning Aurobindo's purported compliance with cGMPs fall short of the threshold of admissibility under the *Daubert* standard, and Aurobindo's response fails to demonstrate that Dr. Lambert provided reliable methodology to reach his opinions.

[1] Ex. 1, Lambert Tr. at 35:8-13; 221:18-222:8; 223:17-19.
[2] Def's Mem., Def. Br., at 4.

***1. Dr. Lambert Defers to FDA To Determine Whether Aurobindo Complied with cGMPs.***

Aurobindo admits that Dr. Lambert never provided an affirmative opinion that Aurobindo complied with cGMPs. Defs'. Mem., p. 1 ("Dr. Lambert did not offer a specific opinion as to whether "Aurobindo complied with cGMPs"). Additionally, in its opposition brief, Aurobindo concedes that Dr. Lambert defers to the FDA's opinion on whether Aurobindo complied with cGMPs as it concerns the manufacture and sale of its VCDs.[3] In doing so, Dr. Lambert cannot ignore the FDA letter to Aurobindo, which states in no uncertain terms that Aurobindo was not in compliance with cGMPs and that its VCDs were adulterated. Ex. 3, APL-MDL 2875-0388792. Dr. Lambert further cannot ignore the fact that the FDA [redacted]. Ex. 4, Rao Tr. at 227:10-228:7. Since experts are only permitted to testify at trial in accordance with the contents of their reports, Dr. Lambert should not be permitted to testify that Aurobindo was in compliance with cGMPs in its manufacture and sale of VCDs. Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii).

***2. Dr. Lambert Offers Opinions That Are Unsubstantiated By Methodology Apart From His Own Personal Experience.***

Aurobindo hopes to preserve Dr. Lambert's testimony based almost entirely on his "cGMP expertise." Def's Memorandum (hereinafter "Def's Mem.") at 4, 6. However, Aurobindo fails to acknowledge that the portions of Dr. Lambert's testimony Plaintiffs seek to exclude contain no citations whatsoever, nor do they contain a reference to Dr. Lambert's experience to support his assertions. In *Joiner*, the Supreme Court explained that nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is based on the *ipse dixit* of the expert. 522 U.S. 136, 147 (1997) (holding that it was not an abuse of discretion for district court to exclude unsupported expert opinion); *see also UGI Sunbury LLC v. A Permanent Easement for 1.7575 Acres,* 949 F.3d 825, 834 (3d Cir. 2020) (Rule 702 reliability threshold requires expert testimony to be

[3] Def's Mem. at 5; Ex. 1 at 35:8-13; 47:18-24; 221:18-222:8; 223:17-19

based on more than "subjective belief and unsupported speculation"). Several cGMP-related opinions provided by Dr. Lambert fall into the class of the subjective, unsubstantiated personal opinions that have been denounced as unreliable methodology. *See, e.g.,* Lambert Rep. at ¶28-29, 89-91, 92-94, 104.

In his report, Dr. Lambert flippantly dismisses the observations made by FDA experts in Form 483s and Warning Letters but fails to give supportable rationales for doing so.[4] At no point in his report does Dr. Lambert directly respond to any cGMP violations noted in any of the 483s or Warning Letters issued to Aurobindo at any of its facilities. Instead, Dr. Lambert simply waves off these observations of noncompliant behavior. But this is insufficient. Dr. Lambert should not be permitted to provide opinions that cGMP violations noted by a federal agency are unimportant with no authority to support his opinion. *See Blue Cross Blue Shield Association v. GlaxoSmithKline LLC,* CV 13-4663, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019) (expert testimony concerning cGMP compliance is excluded because the expert provides no reliable basis for his opinions, instead solely basing his "say-so" opinions on his experience); *see also* Fed. R. Civ. P. 26(a)(2)(B)(i)&(ii).

Similarly, Dr. Lambert provides unsupported opinions in response to Mr. Quick's assessment that Aurobindo had insufficient risk management protocols and inadequate adherence to its standard operating procedures.[5] In fact, as outlined in Plaintiffs' Motion, when asked to identify where in his report he provides an affirmative opinion about Aurobindo's adherence to cGMPs, let alone any methodology for reaching these opinions, Dr. Lambert admits his opinions were "implied."[6] *See* Ex. 2, *In re Paulsboro Derailment Cases,* 746 Fed. Appx. 94, 99 (3d Cir. 2018) (unpublished) ("there has to be some showing that there was some recognized method used in arriving at the opinion"). A report that lacks coherent detail about how the expert arrives at his opinions should be excluded. *Kuhar v. Petzl*

[4] Lambert Rep. at ¶29, 127.
[5] Lambert Rep. at ¶89-91, 92-94 ( [redacted] .").
[6] Ex. 1 at 43:20-44:9.

*Company*, 19-3900, 2022 WL 1101580 at *8 (3d Cir. Apr. 13, 2022). The rules are clear: opinions given by experts must actually be given. Plaintiffs should not be forced to attempt to read Dr. Lambert's mind and guess as to what testimony he may offer. These opinions should therefore be excluded.

### *3. Dr. Lambert Proffers Opinions That Are Not Based on Sufficient Facts or Data and Lack "Good Grounds"*

Aurobindo further attempts to salvage Dr. Lambert's cGMP opinions by citing to paragraphs dealing with specific cGMP issues. *See* Def's Mem. at 4. However, these statements are simply unsupported by the factual record and the governing law. *See Joiner,* 522 U.S. at 146 ("court may conclude that there is too great an analytical gap between the data and the opinion that is proffered"). For example, Aurobindo offers Dr. Lambert's statement that Aurobindo properly oversaw Lantech as an example of what they deem to be an admissible cGMP opinion.[7] While Dr. Lambert does rely on his own experience to state that Lantech did not need to use [redacted], he provides no other support for this statement, nor does he comment at all on Aurobindo's oversight of Lantech.[8] *See UGI Sunbury*, 949 F.3d at 834 (per Fed. R. Evid. 702, expert's testimony must be supported by "good grounds"). These are separate issues.

Dr. Lambert's methodology in asserting Aurobindo properly oversaw Lantech is flawed. In making that determination, one need look no further than the FDA's import ban which was imposed on Lantech after FDA inspectors visited the facility.[9] Dr. Lambert acknowledged that import bans are generally imposed for significant reasons.[10] However, Dr. Lambert failed to consider and, significantly, was not even aware that Lantech was no longer permitted to export products to the United States.[11]

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[7] Def's Mem. at 4.
[8] Lambert Rep. at ¶17(ix), 49-53, 55.
[9] Ex. 4 at 238:8-20.
[10] Ex. 1 at 80:19-82:17.
[11] Ex. 1 at 81:2-11.

While Aurobindo made the affirmative decision to continue using Lantech after finding [redacted] in its 2015 site audit of Lantech's facilities[12], it only took the FDA a single visit to determine that this company should not be selling to or making products for any American consumer.[13] Dr. Lambert simply wrote off these [redacted] as trivial.[14] Dr. Lambert's opinion that Aurobindo adequately oversaw the manufacturing processes at Lantech takes too great an analytical leap to be deemed reliable. *Joiner,* 522 U.S. at 146.

Aurobindo also cited to Dr. Lambert's opinion that Aurobindo had no reason to test for nitrosamines and or utilize gas chromatography-mass spectrometry (GC/MS) to detect the presence of nitrosamines in its VCDs. *See* Def's Mem. at 4; Lambert Rep. at ¶17(iv)-(vi), 131-32. Dr. Lambert, however, provides no authority for his assertion that GC/MS testing was unnecessary or unwarranted. Lambert Rep. at ¶73-76. The fact that the FDA did not publish guidelines earlier on GC/MS testing did not prevent other companies like Valisure from performing these tests and finding nitrosamines in VCDs. Ex. 6 at 476:2-477:10. In fact, in June 2015, Aurobindo completed a [redacted] for a customer who inquired about the absence of [redacted], in Aurobindo's product. Ex. 6 at 65:1-72:13. *See also,* Ex. 7, APL-MDL-2875-2076260. This [redacted] placed Aurobindo on notice that (1) nitrosamines can and do exist in pharmaceuticals, and (2) that it was important for Aurobindo to take appropriate measures to prevent the existence of nitrosamines in their drugs. *Id.* This questionnaire further contained an option for Aurobindo to certify that it [redacted], thus demonstrating that this was a known and accepted method for detecting nitrosamines, even in 2015.

[12] Ex. 6, Singh Tr., at 237:9-17.
[13] Ex. 4 at 238:8-24.
[14] Lambert Rep. at ¶98.

At a minimum, Aurobindo knew that GC/MS testing was available and in fact helpful in detecting nitrosamines in VCDs at least two months before it actually began testing. Aurobindo created, modified, and accessed an FDA document titled "Combined Direct Injection N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by **GC/MS**" in October 2018 – two months before Aurobindo performed LC-MS/MS testing on its product for nitrosamines. Ex. 8, APL-MDL-2875-2803459 (emphasis added and access date shown in metadata). Thus, Dr. Lambert's methodology in reaching his conclusions is nonexistent and directly contradicted by the record.

In short, Aurobindo has failed to expose any reliable methodology or facts which would permit Dr. Lambert from providing testimony on Aurobindo's compliance with cGMPs. Even the examples Aurobindo relies upon lack support and are contradicted by the factual record. *See Apotex, Inc. v. Cephalon, Inc.,* 321 F.R.D. 220, 236 (E.D. Pa. 2017) (expert opinion is inadmissible if it "is both contrary to the record...[and] is contrary to the law").

### B. Dr. Lambert's Stated Basis for VCDs' Value Should Be Excluded Because It Lacks "Good Grounds"

In defending the value of Aurobindo's VCDs, Dr. Lambert improperly dismisses the effect that the adulteration of Aurobindo's VCDs has on any purported value the drugs retained. Further, the authorities cited by Aurobindo are distinguishable because Aurobindo's VCDs were adulterated in a manner that necessitated a recall of its product.

#### *1. Dr. Lambert's Bioequivalence Theory Is Negated by His Admission That It Is Illegal to Sell "Adulterated" Drugs*

Dr. Lambert's value opinion, based on his allegation that Aurobindo's VCDs were bioequivalent to the Reference Listed Drug, is flawed because it discounts the illegality of selling adulterated drugs. An expert's opinion is inadmissible if it "is both contrary to the record…[and] is contrary to the law." *Apotex,* 321 F.R.D. at 236.

First, Dr. Lambert conceded that Aurobindo's VCDs are adulterated under 21 U.S.C. § 351(a)(1).

Q: [redacted]

A: [redacted]

Ex. 1 at 75:14-22. *See also* Ex. 5, Johns Tr., at 98:17-99:2.

Dr. Lambert further admitted that, pursuant to 21 U.S.C. § 331(a), it is illegal to introduce an adulterated drug into interstate commerce:

> Q: The very first thing that it says is prohibited is…"The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." Did I read that correctly?
>
> A: Yes.
>
> Q: Does that suggest to you that this section of the law prohibit the introduction of adulterated drug products into interstate commerce in the United States?
>
> [Objection to form]
>
> A: Given the definition of adulterated in the C.F.R., yes.

Ex. 1 at 103:23-104:19.

Pursuant to this undisputed evidence, Dr. Lambert further agreed if a drug is adulterated, and it is illegal to sell adulterated drugs, that there can be no legitimate supply curve for the adulterated drug. Ex. 1 at 104:21-105:8. In the absence of a legitimate supply curve, Aurobindo's adulterated VCDs are worthless. In *U.S. v. Gonzalez-Alvarez*, the First Circuit agreed that an adulterated product, milk, is worthless because the product's supply curve should have been terminated before the adulterated product was sold; it should not be permitted to acquire an increased value merely because the defendant illegally sold the adulterated product. 277 F.3d 73, 78 (1st Cir. 2002).

Additionally, Dr. Lambert's opinion that Aurobindo's VCDs retained value, due to the alleged maintenance of their therapeutic effect, is futile because the record indisputably establishes that

customers would not knowingly purchase an adulterated product. Aurobindo's Chief Quality Officer, Dr. Ambati Rama Mohana Rao, testified in agreement:

Q: [redacted]

A: [redacted]

Q: [redacted]

[Objection to form]

A: [redacted]

Ex. 4 at 233:14-21. *See also, U.S. v. Marcus*, 82 F.3d 606, 610 (4th Cir. 1996) (recognizing "the unchallenged finding that consumers would not purchase a drug of unknown safety and efficacy at any price").

The question posed to Dr. Rao did not constitute a counterfactual hypothetical[15] because Dr. Lambert confirms that [redacted]. Ex. 1 at 97:12-22; 254:7-18. He even agrees that [redacted]. Ex. 1 256:10-19.[16] Thus, Dr. Lambert's purported value methodology is unreliable because the record and relevant law establishes that Aurobindo VCDs were adulterated, there is no valid supply curve for illegal products, and consumers, including Dr. Lambert himself, would not knowingly purchase contaminated product.

Dr. Lambert further opined that the type of cGMP violations at issue for Aurobindo were not the type of cGMP that "make Aurobindo's VCDs worthless." Def's Mem. at 10. In doing so, Dr. Lambert trivialized Aurobindo's cGMP violations, comparing them to what might happen if a

[15] Def's Mem. at 14.

[16] Defendant's argument at Ex.2, n.5 that Dr. Lambert's choice of the uncontaminated drug is qualified by the fact that there would have been a "drug shortage" is ineffective given Dr. Lambert's prior admission that an illegal drug can have no valid supply curve.

company used a blue pen when a black pen was called for.[17] There is simply no world in which that scenario is comparable to one in which product was pulled off the market due to its contamination. Indeed even Dr. Lambert eventually admitted that Aurobindo's issues were more serious:

> Q: Let me ask you this. Do you believe – do you have an opinion that the cGMP violations at Lantech, which I gather you understand well because you looked at all the relevant documents that speak to that, are a blue ink/black ink cGMP failure or something more significant and material?
>
> [Objection to form]
>
> A: I would agree that they had some issues that were above the blue/black ink issue.

Ex. 1 at 93:16-94:5.

Finally, Aurobindo contends that its products were not all contaminated, but this claim is also suspect.[18] Rather than burdening the Court with repetitive arguments, Plaintiffs hereby incorporates by reference their Response in Plaintiffs' Brief in Opposition to Defendants' Motion to Exclude Opinions of Ron Najafi, pp.19-21, and Reply Brief in Support of *Daubert* Motion to Preclude Defense Expert Jason O. Clevenger From Offering Class Certification Opinions, pp. 7-20, wherein Plaintiffs explain at length why Aurobindo's test results are incorrect and unreliable. Any testimony by Dr. Lambert which relies upon these "low" nitrosamine levels is therefore also unreliable and therefore inadmissible.

Therefore, Dr. Lambert's opinion that Aurobindo's VCDs are not worthless, despite the VCDs not having a valid supply curve and not being reapproved for sale in the U.S., should be excluded on the grounds that it is contrary to undisputed evidence in the factual record and the applicable law. *Apotex,* 321 F.R.D. at 236.

[17] Ex. 1 at 87:3-20.
[18] Def's Mem. at 9.

### *2. Aurobindo's Cited Authorities on Value are Inapposite*

Aurobindo's authorities regarding the alleged value of adulterated drugs are distinguishable. In arguing that their VCDs did retain some value, Aurobindo first relies on *Shahinian v. Kimberly-Clark Corp.,* 2017 WL 11595343 (C.D. Cal. Mar. 7, 2017) and *Ctr. City Periodontists, P.C. v. Dentsply Int'l, Inc.,* 321 F.R.D. 193 (E.D. Pa. 2017).[19] However, neither of these cases involved a recalled product. In *Shahinian*, the defendant sold a MicroCool Gown product that posed an alleged safety issue to health care professionals who wore the gown. 2017 WL 11595343 1, *1 (C.D. Cal. Mar. 7, 2017). The court determined that the holding from *Gonzalez-Alvarez* did not apply to the misbranded gown because the product was never recalled, and the plaintiffs found alternative uses for the product. No alternative uses exist for Aurobindo's VCDs. Similarly, in *Ctr. City Periodontists*, plaintiff's expert report was excluded as unreliable because the report advanced the argument that the non-recalled dentistry product was worthless. 321 F.R.D. 193, 204 (E.D. Pa. 2017). By contrast, Aurobindo's VCDs were recalled because the FDA stated publicly that they pose a serious risk to human health. Moreover, these drugs cannot be reused, and Aurobindo has not been able to resell them to anyone.[20]

Aurobindo also cites *In re Rezulin Prods. Liab. Litig.* to advance its position that recalled drugs can maintain some value despite being recalled.[21] However, in *Rezulin*, the plaintiffs' claims arose out of "known complication[s]" and other side effects that were common. 210 F.R.D. 61, 64 (S.D.N.Y. 2002). Thus, the court held that the drug could not be deemed worthless, due to the known complications, because it was beneficial to many patients. Here, however, the patients did not know and had no way of knowing that Aurobindo's VCDs were contaminated. *See* Ex. 4 at 233:14-21; *see also* Ex. 1 at 97:12-22; 254:7-18. Dr. Rao agrees that if nobody would knowingly buy Aurobindo's contaminated VCD, then it would not be worth anything. Ex. 4 at 235:13-18.

[19] Def's Mem. at 10-11.
[20] Ex. 4 at 225:19-228:7.
[21] Def's Mem. at 11.

Finally, Aurobindo relies on *In re Baycol Prods. Litig.,* 218 F.R.D 197 (D.Minn. 2003) to show that the court cannot accept that recalled medication does not provide any benefit when it provides therapeutic value.[22] However, Plaintiff's claim that Aurobindo's contaminated VCDs were worthless is independent of any therapeutic value Aurobindo's VCD might have retained because Aurobindo's VCDs were contaminated. Since uncontaminated VCDs existed, the contaminated VCDs were rendered worthless because they contained a genotoxic impurity. Just as a customer at a restaurant would return and decline to pay even one cent for an otherwise good plate of food if it was served with a dead cockroach on top, so too would Plaintiffs have declined to purchase their otherwise good VCDs with nitrosamines. Because Aurobindo's authority does not save Dr. Lambert's opinions on value, those opinions should also be excluded.

## III. CONCLUSION

For the foregoing reasons, Aurobindo's arguments concerning (i) Dr. Lambert's opinions related to Aurobindo's compliance with cGMPs, and (ii) Dr. Lambert's opinions regarding the purported "value" of Aurobindo's VCDs. Accordingly, Dr. Lambert's opinions should be precluded as unreliable.

Dated: June 16, 2022

Respectfully,

PLAINTIFFS' CO-LEAD COUNSEL

By: /s/*Ruben Honik*
Ruben Honik
HONIK LLC
1515 Market St, Suite 1100
Philadelphia, PA 19102
267-435-1300 (t)
267-263-7497 (f)
ruben@honiklaw.com

[22] Def's Mem. at 11.